

REMARKS

This Preliminary Amendment constitutes the proper Submission with the RCE being concurrently filed and fully complies with M.P.E.P. § 706.07(h)(II).

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the specification and claims and the following remarks.

Status of the Claims

In the present Amendment, claims 1-22 have been canceled, and new claims 23-40 have been added. Thus, claims 23-40 are pending in the present application.

No new matter has been added by way of these amendments because each amendment is supported by the present specification and the canceled claims. For example, claim 23 has support in canceled claims 1 and 8 and paragraphs [0022], [0050], [0052] and [0057] of the present specification. New claim 24 is similar to claim 2, etc.

Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims. Though all previous rejections have been withdrawn, Applicants note that new rejections are being addressed herein as set forth in the Final Office Action.

Issues under 35 U.S.C. § 103(a)

Claims 1-5, 7, 10-14, 16 and 19-21 stand rejected under 35 U.S.C. § 102(b) as being unpatentable over newly cited **Takeda** (U.S. 2001/0007652) (Office Action at pages 2-4).

Also, claims 8, 9, 17, 18 and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over **Takeda** as applied to claims 1-5, 7, 10-14, 16 and 19-21 above, and further in view of newly cited **Sagel** (U.S. 2003/0219389) (see pages 4-5 of the Office Action).

Further, claims 8 and 9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over newly cited **Tapolsky** (U.S. Patent No. 6,103,266) in further view of newly cited **Friedman** (U.S. Patent No. 5,438,076) (see pages 5-6 of the Office Action).

Applicants respectfully traverse and reconsideration is based on the following remarks. Though these rejections are rendered moot since claims 1-22 have been canceled, the following is submitted in view of the new claims.

The Present Invention and Its Advantages

An object of the present invention is to provide a tooth whitening set and a method for reversibly making teeth look white by changing the optical properties of the enamel without using any peroxide, thereby making teeth apparently look white while permitting teeth to restore their original color in the presence of water from saliva and which keep the whitening effect over a long period of time.

That is, as is disclosed at pages 1 to 3 of the present specification, the method for making teeth look white in the prior art uses chemical procedure such as bleaching with a peroxide.

In contrast, in the present invention, such a peroxide or the like is not used at all as a bleaching agent. The inventive nonaqueous gel composition allows a whitening ingredient (A) having a relative permittivity of 17.0 to 43.0 (at 25°C) and a vapor pressure of 0 to 7000 kPa (such as isopropanol, butanol, ethylene glycol, polyethylene glycol (with an average molecular weight of 190 to 630), diethylene glycol, propylene glycol, dipropylene glycol, butylene glycol, and glycerin) to infiltrate into the enamel to replace water therein, thereby changing the optical properties of the enamel without using a bleaching agent such as a peroxide and thus without accompanying any chemical reaction on teeth enamel such as bleaching.

Moreover, in the nonaqueous gel composition of the present invention, as is disclosed at page 8 and page 11 of the present specification, the ingredient (B) is used for preventing the tooth whitening ingredient, which has penetrated into the enamel, from leaching out of the enamel, thereby allowing the tooth whitening effect to last longer. That is, in the present invention, the composition contains a higher fatty acid or acrylic acid copolymer (as the whitening effect endurance improver (the ingredient (B)) which is dissolved in the tooth whitening ingredient (see also the present specification at, e.g., paragraph [0030] at page 11). When the composition is contacted with water (saliva) in (or on) the enamel, the composition is diluted with water (saliva) and then the higher fatty acid or acrylic acid copolymer is separated out from the dissolved state. The separated higher fatty acid or acrylic acid copolymer prevents the tooth whitening ingredient which has been penetrated into the enamel from easily leaching out so that the tooth whitening ingredient is not easily replaced by water (saliva), thereby the whitening effect will endure for a longer time until the tooth whitening ingredient which has

penetrated into the enamel is gradually replaced by water in saliva, so that the treated teeth restore their original color.

Furthermore, in the present invention, as is disclosed at pages 18 to 20 of the present specification, a special tool (tape, sheet or film) is used for retaining the inventive nonaqueous gel composition on teeth so that the inventive tooth whitening ingredient is surely infiltrated into the enamel to replace water therein by preventing a dilution of the composition by invasion of saliva to the gel composition.

Thus, it is necessary to retain the inventive nonaqueous gel composition on teeth for 1 to 120 minutes, as is disclosed at page 20 (paragraph [0057]) of the present specification, in order to avoid the contact of saliva to teeth. If tooth brushing is conducted for the inventive nonaqueous gel composition as in the conventional dentifrice compositions upon the beginning of use, the infiltration of the inventive tooth whitening ingredient into the tooth enamel would not be attained due to a dilution of the composition by invasion of saliva. Therefore, the composition is retained by the special tool for at least one minute so that the composition is not diluted by saliva. After tooth whitening action, the inventive composition may be wiped off with tissue paper, and the tooth whitening ingredient in the enamel is replaced by water from saliva, thereby going back to the original color of the enamel reversibly.

Therefore, the present invention is directed to the nonaqueous gel composition that is retained for 1 to 120 minutes by the special tool for its application which is fitted to teeth while holding the nonaqueous gel composition and preventing a dilution of the composition by invasion of saliva.

Distinctions over Cited References and Combinations Thereof

Applicants respectfully submit that the new rejections are improper.

Regarding the first cited rejection, the Takeda reference discloses a dentifrice composition for imparting gloss on teeth comprises shellac or wax, and further comprises propylene glycol and/or glycerin. However, in Takeda's composition, propylene glycol and glycerin are used as a solvent, and these polyols are not used as the tooth whitening ingredient.

Furthermore, all of Takeda's compositions in Examples comprise water, and Takeda allows the use of water in the dentifrice composition. In Takeda's composition, water is rather essential, which is in contrast to the present invention (see, e.g., the features in claim 23).

Moreover, Takeda's composition is applied to teeth as conventional application method of dentifrice compositions by tooth brushing upon the beginning of use. Takeda fails to disclose and teach the application of the nonaqueous gel composition by using the special tool (such as tape, sheet, or film) for retaining the inventive gel composition on teeth so that the tooth whitening ingredient is surely infiltrated into the enamel to replace water therein by preventing a dilution of the gel composition. As the M.P.E.P. directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. *See* M.P.E.P. § 2143.03.

In Takeda's composition, the wax or shellac covers the surface of the teeth, thereby smoothing the surface thereof, and it has been considered that irregular reflection of light is prevented, and so, good gloss, brightness and luster can be imparted to the teeth (see page 3, (0039)). Thus, Takeda's tooth glossing action is different from the tooth whitening action of the inventive nonaqueous gel composition. Furthermore, Applicants note that the superiority of the

present inventive gel composition being free of water is evident from the results of Comparison No. 4 which is used the aqueous composition.

Regarding the cited modification of Takeda to account for all claimed features, under *Ex parte Levingood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993) and *Ex parte Gerlach*, 212 USPQ 471 (BPAI 1980), the Examiner cannot equate that which is within the capabilities of one skilled in the art (“one of ordinary skill in the art could adjust the parameters”) with obviousness. Thus, the first rejection in view of Takeda is improper. Takeda fails to disclose and teach the feature of the present invention.

Therefore, the present invention is patentably distinct over the cited Takeda reference and this first rejection has been overcome. Withdrawal of this rejection is respectfully requested.

Also, regarding the second rejection, the cited secondary reference of Sagel is improperly combined with Takeda. Applicants note that combining known prior art elements is not sufficient to render the claimed invention obvious if the results would not have been predictable to one of ordinary skill in the art. *United States v. Adams*, 383 U.S. 39, 51-52, 148 USPQ 479, 483-84 (1966); *see also* M.P.E.P. § 2143. The results of the present invention are not predictable, especially based on the disclosures of Takeda and Sagel.

Sagel discloses tooth whitening products and includes a strip of material to cover the surface of teeth. However, Sagel's products comprise the tooth whitening composition having active peroxide. Sagel's tooth whitening effect may be caused by chemical bleaching reaction due to peroxide. In contrast, the present invention does not use a bleaching agent at all such as a peroxide or the like. Thus, the tooth whitening action of Sagel are clearly different from the

present invention, and also different from Takeda. Thus, the second rejection is improper as well.

Furthermore, as is apparent from its claim 6, Sagel's tooth whitening composition could comprise water, and Sagel allows the use of water in the dentifrice composition. Accordingly, Sagel fails to disclose and teach the concept let alone all features of the present invention.

As is evident from the above discussion, it would have been no reason to combine Takeda with Sagel because of the different action to teeth, respectively, and it would have been impossible to modify the administration of Takeda's composition to use strip of Sagel.

Even if Takeda is combined with Sagel, it would be impossible for skilled artisan to arrive at the inventive tooth whitening set and tooth whitening method for reversibly making teeth look white without chemical bleaching reactions in the present claims from the disclosure of Takeda and in view of Sagel. Applicants note that the invention as a whole is not restricted to the specific subject matter claimed, but also embraces its properties and the problem(s) it solves (e.g., without use of chemical bleaching). *In re Wright*, 6 USPQ2d 1959, 1962 (Fed. Cir. 1988) (“The problem solved by the invention is always relevant. The entirety of a claimed invention, including the combination viewed as a whole, the elements thereof, and the properties and purpose of the invention, must be considered”); *In re Sponnoble*, 160 USPQ 237 (CCPA 1969). Applicants respectfully request consideration of how the present invention does not use chemical bleaching reactions.

Therefore, the present invention is patentable despite the disclosures in Takeda and Sagel. Withdrawal of this rejection is respectfully requested.

Regarding the third rejection, Tapolsky and Friedman fail to disclose and teach the features of the present inventive tooth whitening set and tooth whitening method. Reconsideration is respectfully requested in view of the new claims now pending.

Reconsideration and withdrawal of all rejections are respectfully requested.

Conclusion

In view of the above amendment, Applicants believe the pending application is in condition for allowance. A Notice of Allowability is respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez (Reg. No. 48,501) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

**Application No. 10/584,192
Preliminary Amendment with RCE
After Final Office Action of March 11, 2009**

Docket No.: 0171-1287PUS1

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

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